

# What is EHES and why is it needed?



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## Summary

### Background

- Major chronic diseases contribute to 86% of deaths and disability in Europe. For the working age population (below age 65), these are the major causes of premature mortality and work disability, preventing healthy ageing.
- The burden of these diseases varies considerably between countries and socio-economic groups.
- Many of the diseases are preventable through known risk factors: smoking, blood pressure, cholesterol composition, obesity and diabetes.
- The distributions and changes of the risk factors are known only from some European countries, and even from these the information is not comparable.

### The European Health Examination Survey (EHES)

- EHES is a collaborative activity between European countries and the EU to provide comparable information on the major chronic disease risk factors in the European adult population. This information will provide an evidence base for policy making, evaluation of preventive activities and research.
- EHES complements data from registries and the European Health Interview Survey on aspects where these do not provide objective information. Some of the key information is obtainable only through a health examination survey.
- EHES can be extended to cover other measurements, such as lung function and functional capacity of the elderly.
- The national surveys are organized and carried out by national organizations. The surveys are costly, but the cost is low compared to the potential savings from successful prevention of the diseases.

### Status of EHES

- Feasibility study has shown that EHES is doable. It should be started urgently to get already planned national surveys under joint standardization.
- Pilot study is successfully ongoing:

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- to prepare for and pilot EHES in 13 countries (Czech Republic, Finland, Germany, Greece, Italy, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Spain and UK/England);
  - EHES Reference Centre for European level coordination, standardization, training, evaluation and reporting has been established.

### **The next steps**

- To implement the full-size surveys in these countries;
- To plan and implement health examination surveys in other countries, targeting to a sustainable EHES system in Europe.
- To get the next steps funded. Support from the EU would be needed for the European level activities and desirable for partial support of the national surveys. The national activities would be covered mostly from national sources.

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## 1. Introduction

Chronic diseases are a major cause of deaths (86%) and disability in Europe<sup>1</sup>. They affect largely the working age population through premature death and work disability, preventing healthy ageing. This has also large economic implications directly through health care costs and indirectly through lost productivity. In the EU, cardiovascular diseases alone cost 192 billion euro a year, of which 57% is direct health care costs, 21% due to lost productivity, and 21% due to informal care provided by relatives and friends<sup>2</sup>.

The burden of these diseases varies considerably between countries and socio-economic groups<sup>1</sup>.

Many of the major chronic diseases, such as lung cancer, cardiovascular diseases and diabetes are preventable through their key risk factors, which are smoking, blood pressure, blood cholesterol composition and obesity. Accordingly, prevention of chronic diseases is one of the objectives of the implementation of EU's Health Strategy<sup>3</sup>. OECD data shows that 97% of the annual health expenditure goes for healthcare and treatment, and only 3% for prevention in the Member States<sup>4</sup>.

Information about the health and health risks of the population is one of the cornerstones of prevention. It is needed for evidence based planning and evaluation of health policies and preventive activities. Some of population level information, such as mortality, can be obtained from registries. Some can be obtained from interview surveys, such as the European Health Interview Survey (EHIS), which is being developed under the leadership of EUROSTAT. A third data source, which complements registries and interview surveys, by providing information which cannot be obtained objectively or at all from other sources is a health examination survey (HES). This concerns information in blood pressure, blood cholesterol, blood glucose, which is an indicator of diabetes, and objective information on obesity.

Currently some European countries have conducted representative nationwide health examination surveys, but these are not standardized to provide comparable data. In most countries no nationwide HES data are available. The Feasibility of a European Health Examination Survey project<sup>5-7</sup>, completed in 2008, found that

- it is feasible to carry out a national HES in nearly all EU countries;
- the national contact persons of the project, who represented primarily instances that have expertise on HES and could conduct such a survey, considered comparability between countries important; and
- action for European level standardization should be initiated urgently so that the surveys that were already being planned could be standardized.

DG SANCO of the European Commission took up the challenge and decided to support an EHES Pilot Project. The objective of the Pilot project was to



- prepare for and pilot EHES in 13 countries, which were planning to start a national HES in the near future, and
- to set an EHES Reference Centre to take care of the European level coordination, standardization of measurements, training, evaluation of the surveys and reporting of the results.

The Pilot project is proceeding well. By the end of year 2011, the piloting countries are ready to start a full-size national survey provided that they have the funding. Four of them have already started the survey.

The vision of EHES is to become a sustainable system of national health examination surveys, covering all EU and EFTA/EEA countries. It would provide nationally representative, high quality, comparable information to support the planning and evaluation of health policies and preventive activities. EHES is a combination of data collection and research. Research is needed for further improving the data collection methods and for translating the data into interpretable information for the benefit of public health. The unique collection of population based data and biological samples should be used widely for research.

Decisions of the funding of the European level infrastructure of EHES from year 2012 onwards are pending. The purpose of this document is to describe EHES and justify the importance of its various components.

- A European level initiative to collect nationally representative, comparable and high quality health data on adults.
- Nationally representative sample of 4000 persons.
- Core measurements: height, weight, waist circumference, blood pressure, total and HDL-cholesterol and fasting glucose.
- EHES Reference Centre is responsible for coordination of EHES.

## 2. What is EHES

European Health Examination Survey (EHES) is an initiative to set up a system of standardized, representative health examination surveys (HES) of the adult population of the European countries. In the background is a demand by countries and the European Commission for evidence about the health and health risks of the population. This is needed for the planning and evaluation of health policies and preventive actions. Health and health risks, which predict future health, are key issues for keeping the work force fit for work and to minimize the need for health care for the aging population.

EHES provides health indicators of major public health problems, such as prevalence of high blood pressure and diabetes in the population, which cannot be obtained, at least with a reasonable cost, through any other data source. Therefore, it is complementary to registries (such as cause of death registries and health service registries) and health interview surveys (such as EHIS - the European Health Interview Survey).

The core measurements, which are expected to be included in every national HES are

- **Height, weight and waist circumference** to measure body composition. Obesity is a strong risk factor for hypertension, diabetes and osteoarthritis. It contributes to 10-13% of deaths in Europe<sup>8</sup>.
- **Blood pressure**, which is a major modifiable risk factor of cardiovascular disease (CVD). CVD is the leading cause of disability in Europe <sup>2</sup>. Blood pressure distribution is a strong indicator of the burden of hypertension in the population. The percentage of people with elevated blood pressure who are unaware of the condition is an important indicator of the performance of the health care system and is likely to vary substantially between countries.
- The role of **blood lipids** composition is very similar with that of blood pressure.

- **Fasting blood glucose** is an indicator of diabetes. It seems that this can be replaced within the next few years with the measurement of glycated haemoglobin, which is easier to measure precisely in a HES, but which for the time being is a more expensive measurement.<sup>9</sup> There is indication that up to 40% of those with type 2 diabetes may be unaware the condition.<sup>10, 11</sup>
- Every HES should include a selected set of **Questionnaire items** which are important to know from the same persons on whom the examination measurements are done.

Most countries will include a variable set of additional items based on national interests, past experience on HESs and funds available for the survey. It is strongly recommended that the countries collect more blood than is needed for the EHES core measurements. This will form the basis for national biobanks which can be used for measurement of additional, currently known or forthcoming, biomarkers. Where feasible, also DNA will be collected, and some countries consider establishing a cell line.

A study on the feasibility of EHES was carried out in 2006-2008.<sup>5-7</sup> It revealed that:

- Only few countries had a system of repeated national HESs (England and Scotland, Finland, Germany, Ireland, Netherlands and Poland).
- It is technically feasible to carry out a national HES in practically all Member States and EFTA/EEA countries.
- 17 countries had a plan to carry out a national HES in the next five years, although there was often no final decision on this yet.
- All of these considered it important that their data be comparable with the data from other countries, and thought that international collaboration will be needed to achieve this.
- European level coordination of the national HESs should be set up urgently in order to get all the forthcoming HESs under joint standardization.

Following the recommendations of the feasibility study, the EHES Pilot Project was started in 2009. Its aim was:

- To set up EHES Reference Centre (EHES RC, see page 19 for details);
- To prepare for a full-size national HES in the first 13 countries (Czech Republic, Finland, Germany, Greece, Italy, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Spain and UK/England) including training and a fieldwork pilot of 200 examinations (Figure 1); and
- To prepare a national HES manual for all Member States and EFTA/EEA countries.



**Figure 1.** EHES Pilot countries

The Pilot Project is proceeding as planned. In fact, four of the countries have already started a full-size HESs (Germany, Netherlands, Italy, and UK/England) and the others are technically ready to start it around the end of year 2011. In many countries the funding is still pending. Outside these Pilot Project countries, also France and Luxembourg have now decided to start a national HES. France will start in 2013 and Luxembourg in 2012. France has participated in the EHES training and both countries have been active in the EHES network.

EHES collaborates with national HESs outside Europe, such as the NHANES of the USA<sup>12</sup>, Canadian Health Measures Survey (CHMS)<sup>13</sup>, Australia and the STEPwise approach to chronic disease risk factor surveillance<sup>14</sup> developed by the WHO for low and middle income countries.

### **Target population and population sampling of EHES**

The target population of EHES, which should be covered in every country, is the 25-64 year old residents of the countries. Knowledge of risk factors and detection of emerging chronic diseases at this age is important for the prevention of future diseases and disability. Countries may extend their survey to all adults above age 18, and cover additional topics relevant to the elderly, such as functional capacity. It is recognized that information on children is also valuable, but they are not included in EHES at this stage because they need different survey approaches.

The sample should be based on probability sampling covering entire country. Therefore, patient records are not sufficient.

Where possible, immigrants and institutionalized persons should be included in the national survey. However, in some cases they may not be listed in the sampling frames that are available.

The invitees to the survey are selected using the best available sampling frames (i.e. the lists of the residents of the country) using probability sampling. This guarantees that the samples represent the real population, and it also facilitates the estimation of the precision of the health indicators derived from the survey.

The minimum sample size of 4000 persons is needed to get sufficiently precise estimates, which also allows the comparison of population subgroups, such as socio-economic categories. EHES pays particular attention to ethical and data confidentiality issues as well as to achieving high participation rates, which guarantee the representativeness of the survey.

- HIS and HES are complementary. Also a HES includes always a questionnaire part.
- The organization of HES requires a wider range of professionals than HIS
- HIS provides self-reported data which sometimes suffers from severe reporting bias, for example:
  - Under-estimation of prevalence of obesity
  - Over-estimation of physical activity
  - Many of those with diabetes are unaware of their condition

### **3. Difference between HIS and HES**

#### **Organization of HIS and HES**

Health interview survey (HIS) is a questionnaire based survey. It can be conducted as

- a mail survey, where the questionnaire is mailed to the selected persons for self-completion,
- a telephone interview, or
- face-to-face interview, where the interviewer goes to the selected persons and conducts the interview.

All information in a HIS is based on self-reports of the respondents. In a telephone or face-to-face interview, the fieldwork is carried out by trained interviewers, with support from coordination and technical personnel.

In a health examination survey (HES), some of the information is questionnaire based, such as background variables education and income, but an essential part of the survey are physical measurements and collection of biological samples. The physical measurements and collection of biological samples require careful ethical consideration, including an Ethics Committee approval and written informed consent from the participants. Also attention needs to be paid on the selection of personnel as, for example, the legislation may regulate who can take for example blood samples and provide results of the health measurements to the participants.

#### **Reliability of data collected by HIS and HES**

In a HIS, information is obtained by asking people to report their health behaviours, health status and diseases. This suits well for questions on opinions, attitudes and perceived health. However, for many factual questions there is reporting bias

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because of the person's personal wishes or the person may be unaware of the true situation. Examples of this are blood pressure, blood cholesterol levels and also body height and weight. These can be measured reliably only in a HES.

These differences for relevant HES measurements are discussed in more detail below.

### **Self-reported vs. measured height and weight**

A number of studies has shown that self-reported weight is under-estimated and height over-estimated. This results in under-estimation of prevalence of obesity in the population. Men tend to over-report their height more than women and women tend to under-report their weight more than men. The reporting bias is dependent on age. Over-reporting of height and under-reporting of weight increase with age. The under-reporting of weight is also dependent of the weight of the person. Those who are overweight or obese tend to under-report their weight more than those who are of normal weight.<sup>11, 15, 16</sup> Also cultural differences are possible.

### **Self-reported elevated total cholesterol level**

About 20%-60% of the population is unaware of their cholesterol level<sup>11, 17</sup>, and therefore this cannot be measured reliably in a HIS. Studies have also shown that there is a difference between those who are aware and unaware of their cholesterol levels. Those who are aware are more often from higher socio-economic classes and have healthier behaviours.

### **Self-reported hypertension**

When comparing self-reported hypertension prevalence, i.e. those who have had their blood pressure measured and have been told to have hypertension, to the hypertension prevalence based on measured blood pressure and known medical treatment of hypertension, the self-reported prevalence is 10%-60% lower<sup>10, 11</sup>.

### **Self-reported diabetes**

When comparing self-reported diabetes, i.e. those who say that they have been diagnosed to have diabetes, to the measured blood glucose levels, up to 40% of those with diabetes are unaware of their condition<sup>10, 11</sup>.

### **Self-reported physical activity**

Self-reported physical activity in comparison to the physical activity log or objective measures by accelerometers tend to overestimate physical activity in both men and women, and more so in men. Among younger age groups and persons with lower BMI, the overestimation of the physical activity is higher in comparison to others<sup>18</sup>.

### **Open questions about reporting bias**

We know that many relevant health indicators which are based on self-reported data, have reporting bias. If we knew that the reporting bias was always constant, these health indicators could still be useful. However, there are critical open questions:

- Is reporting bias the same in all European countries or are there geographical differences?
- Is reporting bias the same in all socio-economic groups?
- Is reporting bias the same in all age groups?
- Is reporting bias stable over time or is it changing?
- Are the possible differences between socio-economic and age groups stable over time in all countries?

Before any correction factors can be calculated for self-reported estimates obtained from a HIS, HES data are needed to evaluate these questions.

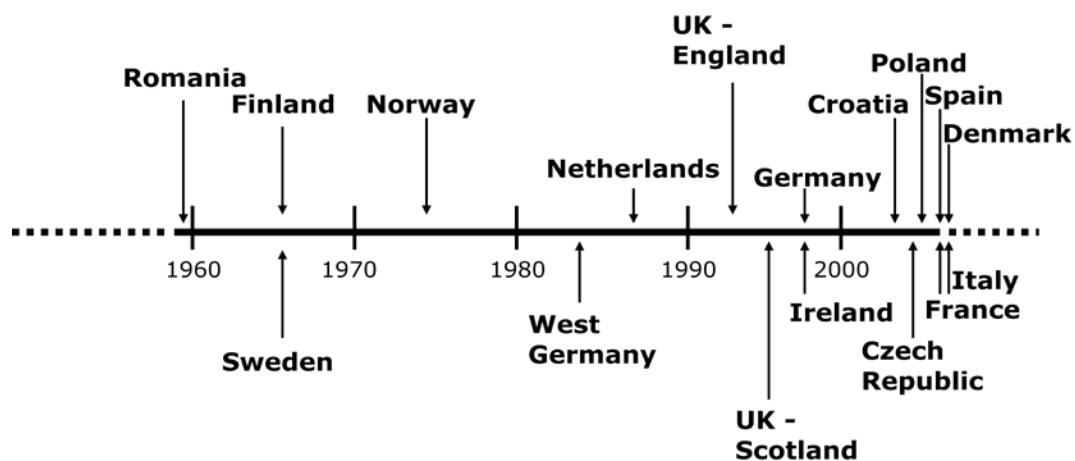


- The 1<sup>st</sup> HESs in Europe were conducted in the 1960s.
- In 2000-2010, a national HES was conducted in 12 EU Member States.
- In 2011, five countries have either an ongoing or will start a national HES.
- 11 countries are planning to have their national HES in 2012-2015.

## 4. Status of HESs in Europe

### History

In Europe, the first health examination surveys (HES) were conducted already in the 1960s (Figure 1). Since then, nationally representative HESs have been carried out in 15 European countries. Additional to these national HESs, in most countries at least some regional or disease specific HESs have been conducted <sup>6</sup>.



**Figure 1.** History of national HESs in Europe

Most of the past HESs have not been repeated in regular basis. Repeated national HESs, which provide data on trends, have been carried out only in Finland, Germany, Ireland, Netherlands, Poland and UK – England and Scotland. <sup>6</sup>

Between 2000-2010 <sup>19</sup>, a national HES was conducted in 12 EU Member States and in five of these more than once (Table 1).

**Table 1.** National or large regional HESs in Europe in 2000-2010

Country	Year	Survey
<b>Cyprus</b>	2000	Risk Factor (CINDI) Survey on Non-communicable Diseases in Nicosia District
	2000	Population Risk Factors Survey
<b>Czech Republic</b>	2004	Health Lifestyle and Environment (HELEN)
<b>Denmark</b>	2007	KRAM
<b>Finland</b>	2000	Health 2000
	2002	Finrisk 2002
	2007	Finrisk 2007
<b>France</b>	2006	National Survey on Nutrition and Health (ENNS)
<b>Germany</b>	2003	KiGGS – The German Health Survey for Children and Adolescents
<b>Ireland</b>	2002	Survey on Lifestyles, Attitudes and Nutrition (SLAN)
	2007	Survey on Lifestyles, Attitudes and Nutrition (SLAN)
<b>Netherlands</b>	2001	Netherlands Health Examination Survey
	2009-2010	Netherlands Health Examination Survey (NL de Maat)
<b>Poland</b>	2005	National Multicenter Health Survey - Project WOBASZ
	2006	National Multicenter Health Survey in the Elderly, WOBASZ Senior
<b>Slovakia</b>	2003	CINDI Health Examination Survey
<b>Spain</b>	2007	Estudio de Nutrición y Riesgo Cardiovascular en España (ENRICA)
<b>UK/England</b>	Annually 2000-2010	Health Survey for England
<b>UK/Scotland</b>	2003, annually 2008-2010	The Scottish Health Survey

## Current status

In 2011, national HESs are ongoing or will be started in five countries (Table 2).

**Table 2.** Ongoing national HES and national HES to start in 2011 in Europe

Country	Year	Survey
<b>Finland</b>	2011-2012	Health 2011
<b>Italy</b>	2008-2012	Epidemiologic Cardiovascular Observatory (OEC)
<b>Germany</b>	2008-2011	German Health Interview and Examination Survey for Adults (DEGS)
<b>Slovakia</b>	2011-2012	<i>Name of the survey not known, will follow the Slovakian EHES pilot</i>
<b>UK/England</b>	2011	Health Survey for England
<b>UK/Scotland</b>	2011	Scottish Health Survey

## Future

During the next three years (2012-2015), at least 11 countries are planning to conduct a national HES (Table 3). In many of the countries there is no decision on the funding yet.

**Table 3.** Countries which have indicated that they are planning to conduct a national HES in 2012-2015

Country	Year	Survey
<b>Czech Republic</b>	2014	<i>Name of the survey not known</i>
<b>Greece</b>	2012	<i>Name of the survey not known, will follow the Greece EHES pilot</i>
<b>Finland</b>	2012	Finrisk 2012
<b>France</b>	2013	National Survey on Nutrition and Health (ENNS)
<b>Ireland</b>	2014	Subsample of EHIS
<b>Luxembourg</b>	2012	<i>Name of the survey not known</i>
<b>Malta</b>	2014	In connection to EHIS
<b>Norway</b>	2013	<i>Name of the survey not known</i>
<b>Poland</b>	2012-2013	EHES Poland
<b>Portugal</b>	2012-2014	Subsample of EHIS
<b>UK/England</b>	Annually 2012-2015	Health Survey for England

## Comparability of the national HESs

Comparability of the national HESs in past has been limited due to differences in included age groups and used survey methods. Many of the HES measurements are sensitive to the used measurement protocols and devices.

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For example, blood pressure measurement is very sensitive to participant's behaviour before measurement, posture during the measurement and the used measurement device. Differences in activities just before the measurement may results up to 20 mmHg, posture during the measurement up to 15 mmHg and use of wrong cuff size up to 40 mmHg difference in the measured blood pressure level<sup>20</sup>.

By proper standardization of the measurement protocols and thorough training of the survey personnel, these differences can be minimized and the comparability of the results ensured.

During the feasibility project (FEHES)<sup>5-7</sup>, contact persons in the EU Member States and EFTA/EEA countries expressed their strong demand for international standardization of the HES methods. They were also looking for international coordination to ensure comparability of the national results. The same message has been obtained from the EHES Pilot countries. In addition to getting information about their national situation, it is important for the countries to be able to compare their results with other European countries. The countries also want to learn from each other, not only on survey methods and techniques, but also on success stories in disease prevention.

One objective of the EHES pilot project has been to assess the possibility to harmonize the countries with ongoing national HESs or a system of periodically conducted national HESs to the EHES standards. The problem has shown up to be smaller than was anticipated. These countries have evaluated the comparability of their existing protocols and the EHES protocol, and assessed the possible effects of a change in procedures to their national trends of the health indicators.

- Research is needed to convert the data into useful information.
- Research is also needed to further develop the survey methods.
- Research relevant to public health policies needs fresh data and repeated surveys.
- The EHES database and biological samples will form a unique resource for research. It is important to ensure that the data will be used widely for research.
- Research training should be an integral part of the national capacity building.

## **5. Relationship between data collection and research in EHES**

EHES is a combination of data collection, research and dissemination of results. New data will obviously be needed from countries where there are no earlier HESs. Fresh data will be needed periodically (about every 5 years) also from countries where there are earlier HESs in order to monitor changes in the health indicators. It is only through research that the resulting survey data can be converted into evidence to support policy making and evaluation of health promotion activities. Research is also needed to develop and evaluate the survey methods.

Much of the necessary development of HES methods has already been done, so that EHES has been found feasible to conduct. However, further high level innovative research will be needed to tackle new challenges and to widen the scope of EHES to cover new health topics. Examples of these are the increasing problem of non-response, which threatens the representativeness of the surveys, and the most likely forthcoming ban of mercury sphygmomanometers in blood pressure measurement. In the latter, the requirements of population surveys are quite different from those of clinical work. Examples of challenging health topics are physical activity, fitness and functioning, and nutrition. Much work has been put to these in the recent years, but the ideal solutions for population surveys are still lacking.

Important research topics for converting the EHES data into useful interpretable indicators include:

- Assessment of the health and chronic disease risk factor patterns in the countries and across Europe, to see where each country is with respect to

living habits and quality of health services. As an example of the latter, there is likely to be major differences between countries in how well those with hypertension or diabetes are aware of their condition.

- Derivation of the role of different risk factors on mortality and major chronic diseases in each country and assessment of the prevention potential related to each modifiable risk factor.
- Assessment of socio-economic differences of diseases and risk factors and evaluation of the means for diminishing these.
- Projections of future disease incidence for different scenarios of risk factor development.
- Methods for transferring EHES findings into improved health.
- Methods for taking non-response optimally into account in data analysis and interpretation of the results.

EHES will create a unique database of standardized data which, together with the biological samples stored for future needs, form a valuable resource for research. It is anticipated that most of the countries will eventually follow up the survey participants for death and development of diseases, which will further increase the research potential of this population based data source.

- Countries will carry out the surveys, obtain funding, analyze and disseminate the results nationally.
- EHES Reference Centre will coordinate EHES, provide support to the countries, organize training and external quality assessment, do joint analysis and reporting.
- Research community will turn the data into useful information for the benefit of health.
- European Union oversees the European level activities.

## 6. How to organize EHES

The Feasibility of the European Health Examination Survey (FEHES) study made recommendations for Organizing EHES<sup>5</sup>. The key players of the organization, which has been strongly supported by the experience from the Pilot study, are countries, EHES Reference Centre, research community and European Union.

The responsibility of the **countries** is to:

- *Carry out the national surveys.* The responsibility of planning and conducting the future HESs should be at the national level. This increases local motivation for obtaining high quality results, possibly increases the participation rate and is important for the selection of those measurements that are most important nationally. The national infrastructure and other national aspects such as habits, public and professional attitudes and health information needs can be taken into account. This approach also facilitates the capacity building in the countries and training of national experts for the proper analysis and interpretation of the survey results.
- *Fund most of the national survey.* A partial EU contribution to the costs would lower the threshold for national funding in the countries. Furthermore, it would help to ensure that each survey meets the minimum size and measurement requirements, and that the individual-level data can be transferred for joint analysis.
- *Analyze the data and disseminate results.* The purpose of the survey is to provide processed information widely for health policy planners and decision makers, health professionals, the general public, and researchers. The countries should have a key role in this in the national level.

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The **EHES Reference Centre**, funded by the EU, is responsible for:

- *Coordinating the EHES network* of all EU and EFTA/EEA countries.
- *Supporting countries* in planning and preparation of the national surveys, such as preparation of national manuals, sampling, ethical issues and data management.
- *Organizing training* seminars and preparation of training material.
- *External quality assessment (EQA)*, including evaluation of survey plans, site visits during the pilot and full-size surveys and laboratory quality assessment. Laboratory standardization which meets the requirements of comparisons between countries and over time within countries does not currently exist in Europe.
- *Data collection* for survey evaluation *and joint analysis and reporting*. This will facilitate rapid assessment of the quality of the data from each country and European level reporting and dissemination.
- *Evaluation* of each national HES and EHES as a whole. The experience needs to be documented for future HESs. The quality and country specific characteristics of each HES need to be documented so that those who analyze the data can take these into account in their analysis and interpretation of the results.
- *Maintaining the EHES database and sharing analysis data sets* with research groups. There is a desire to encourage the use of the data widely for public health benefit while maintaining the legitimate interests of the countries which collected the data. Research collaboration should also help to increase the capacity of all countries to analyse the data on the different health aspects covered by EHES.

The **research community**, nationally and internationally, has the responsibility to *convert the EHES data into useful interpretable information* for the benefit of public health. Another task of the research community is to evaluate and develop survey methods to even better meet the future needs.

The role of the **European Union (EU)** is to:

- *Facilitate and oversee the EHES*, to ensure that it meets its European level and national objectives, and operates in harmony with WHO, OECD and other international agencies.
- *Fund the European level activities*, such as the EHES Reference Centre, and meetings for countries to share their experiences and plan for the future.
- *Provide partial funding for the countries carrying out surveys*. The pilot phase of EHES has shown that this makes the national fund raising much easier. It



also helps to ensure that each survey meets the minimum size and measurement requirements, and that the individual-level data can be transferred for joint assessment and reporting.

- The *EHES database* and collection of biological samples will form a unique resource for research, which should be of major *interest to the European research programmes*.

### The budget for EU-funding for the next phase of the EHES (2013-2017) is around 30M € including

- general coordination and dissemination of the project,
- activities of the EHES Reference Centre ,
- support to 20 countries for data collection,
- extensive research using the HES data, and
- administrative and working meetings of the project.

## 7. Budget for next phase

The budget for EU-funding for the next phase of the EHES (2013-2017) is about 30M € (Table 4). This covers

- general coordination and dissemination of the project,
- most of the activities of the EHES Reference Centre (RC),
- a contribution to data collection in 20 countries,
- extensive research on data already collected and to be collected during the project, and
- administrative and working meetings of the project.

The breakdown of the budget is given in Table 4 and more detailed description and justification of budget items after the table.

**Table 4.** Breakdown of the budget for funding from EU for the next phase of EHES

Item	Cost €
<b>Project coordination and management</b>	400 000 €
<b>Communication, dissemination and publicity (EHES brand)</b>	300 000 €
<b>Scientific Advisory Committee (SAC)</b>	20 000 €
<b>Ethics Advisory Board (EAB)</b>	20 000 €
<b>Data collection by HES in 20 countries (an average of 750 000 € / country)</b>	15 000 000 €
<ul style="list-style-type: none"> <li>• <i>Planning of the national HES</i></li> <li>• <i>Piloting of the national HES protocol</i></li> <li>• <i>Conducting the fieldwork of the national HES</i></li> <li>• <i>Analysis and reporting of the results of the national HES</i></li> <li>• <i>Evaluation of the national HES</i></li> <li>• <i>Data transfer to EHES RC</i></li> </ul>	

<b>EHES Reference Centre</b>	<b>6 000 000 €</b>
<ul style="list-style-type: none"> <li>• <i>Maintaining EHES network</i></li> <li>• <i>Supporting countries in planning and preparing for their national HES, including among other things</i> <ul style="list-style-type: none"> <li>○ <i>sampling (finding out the best design for countries)</i></li> <li>○ <i>ethical consultation (how to prepare an application for the ethical approval, what should be include to the information letter and informed consent)</i></li> <li>○ <i>data management (ways to organize data management in coordinating centre and on the field)</i></li> </ul> </li> <li>• <i>Organizing European level training seminars and preparing training materials</i></li> <li>• <i>External quality assurance (EQA), including</i> <ul style="list-style-type: none"> <li>○ <i>evaluation of the HES plans</i></li> <li>○ <i>site visits to evaluate the fieldwork and to discuss about the organization: during the pilot survey and during the full-size HES</i></li> <li>○ <i>laboratory quality control</i></li> </ul> </li> <li>• <i>Data collection</i> <ul style="list-style-type: none"> <li>○ <i>Preparation of the standardized procedures and tools</i></li> <li>○ <i>Transfer of data on</i> <ul style="list-style-type: none"> <li>▪ <i>sampling and participation status</i></li> <li>▪ <i>measurements</i></li> <li>▪ <i>questionnaires</i></li> </ul> </li> </ul> </li> <li>• <i>Evaluation of</i> <ul style="list-style-type: none"> <li>○ <i>national HESs</i></li> <li>○ <i>EHES as a whole</i></li> </ul> </li> <li>• <i>Maintaining the EHES database</i></li> <li>• <i>Sharing analysis data sets with research groups, including</i> <ul style="list-style-type: none"> <li>○ <i>management of data sharing process</i></li> <li>○ <i>management of data request approvals</i></li> <li>○ <i>data transfer agreements (DTAs)</i></li> <li>○ <i>shared data preparation and transfer</i></li> <li>○ <i>follow-up of progress of data analysis</i></li> </ul> </li> </ul>	
<b>Research to support public health policy making (on average 750 000 € / topic)</b>	<b>3 750 000 €</b>
<ul style="list-style-type: none"> <li>• <i>Health and chronic disease risk factor patterns</i></li> <li>• <i>Assessment of the role of different risk factors for mortality and major chronic diseases by country</i></li> <li>• <i>Socio-economic differences in health and chronic disease risk factors</i></li> </ul>	

<ul style="list-style-type: none"> <li>• <i>Disease projections</i></li> <li>• <i>Methods for transferring EHES findings into improved health</i></li> </ul>	
<b>Research on development of HES methods (on average 750 000 € / topic)</b>	3 000 000 €
<ul style="list-style-type: none"> <li>• <i>Methods to improve participation rates and to tackle non-participation in analyzes and interpretation of data</i></li> <li>• <i>Validation of measurement instruments and standardization of methods</i></li> <li>• <i>Methods for additional EHES measurements</i></li> <li>• <i>Biobanking</i></li> </ul>	
<b>Annual plenary meetings</b>	600 000 €
<ul style="list-style-type: none"> <li>• <i>5 meetings, 60 persons / meeting, 2 days / meeting</i></li> </ul>	
<b>Research WP working meetings</b>	810 000 €
<ul style="list-style-type: none"> <li>• <i>9 WPs, 3 meetings / WP, 15 persons / meeting, 2 days / meeting</i></li> </ul>	
<b>Countries' and WP leaders' meetings</b>	280 000 €
<ul style="list-style-type: none"> <li>• <i>4 meetings, 35 persons / meeting, 2 days / meeting</i></li> </ul>	
<b>TOTAL</b>	<b>30 180 000 €</b>

### Description and justification of budget items

#### SAC

Scientific Advisory Committee (SAC) of 5 members should include experts from public health research, disease aetiology research, chronic disease prevention research, major national HES outside Europe, such as NHANES of the USA, and the WHO.

The SAC should meet 3 times during the five year project period.

#### *Data collection by HES in 20 countries*

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For evidence based public health decisions and for research, high quality, representative and comparable data is needed. Existing data in European level are not comparable and in many countries they are not fresh and nationally representative. Therefore, it is essential that nationally representative high quality data are collected during the project using standard procedures.

The countries will be responsible for planning and carrying out their national HES based on EHES protocols. A well planned HES includes a pilot survey, during which the national HES protocol and logistics solutions are tested. After the pilot survey, necessary adjustments are made to the protocol of the full-size national HES, the personnel are trained and the fieldwork is conducted. Depending on size of the survey and the country, the fieldwork may take from few months to couple of years.

It is important that the HES results are reported nationally as well as in joint reports in European level. For purpose of joint reporting and evaluation of the data quality, the national HES data are transferred to the EHES RC.

After each survey, an evaluation of the work is needed. This evaluation should include all parts of the survey starting from the planning, piloting, training, fieldwork of full-size HES, budgeting, data management to reporting and final dissemination of the results. Evaluation should be prepared so that lessons learned are well documented and can be used in future when next HES in the country is planned.

The total cost of a national HES including the EHES core measurements varies between one and five million euro, depending on the distances in the country, availability of infrastructure (premises, equipment, sample storage etc.) in the beginning of the survey, and the salary rate.<sup>6</sup> An estimate for the average cost is 2.5 – 3 million €. The average EU contribution of 750.000 € used in Table 4 should be sufficient for the countries to help to raise the rest of the funding locally.

#### *EHES Reference Centre (RC)*

EHES RC is needed to coordinate the EHES survey activities and take care of the European level standardization. A European level EHES network of HES experts in all EU Member States and EFTA/EEA countries (except Liechtenstein) has been established during the pilot phase of EHES. It is essential to maintain this network for sharing of information and expertise.

The EHES RC is responsible for maintaining and developing the European level standardized survey protocol. It will also provide support to the countries in planning and preparing for their national HES. This support covers all aspects of the national HES. Especially consultation is often needed on sampling issues as there is limited experience in Europe how to draw representative sample for the national HES. EHES RC will provide support to the countries which do not have prior experience in preparing an information letter and informed consent form. EHES RC will also give

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advice on data management for both centralized data management and for data collection on the field.

One of the key tasks of the EHES RC is to provide European level training on the use of the standardized EHES protocols. Training seminars will be organized periodically and it is assumed that personnel responsible for planning and organizing the national HES will participate to these. There will be training seminars for:

- planning and preparing for the national HES,
- fieldwork procedures for the HES, and
- analysing and reporting HES results.

Well organized external quality assessment (EQA) ensures the high quality and comparability of the collected data. The main components of the EQA organized by EHES RC are:

- evaluation of the HES plans,
- site visits during survey field work, and
- external laboratory quality assessment.

When experts in the EHES RC evaluate the national HES plans before the actual fieldwork is started, deviations from the EHES protocol can be detected and corrected before the data collection starts. Often the evaluation also reveals that some issues have been overlooked, or by doing something differently saves time and money.

Site visits are needed to monitor compliance with the written national HES protocols in practice. Usually a site visit takes two full days: one day observing the field work and the second day discussing the observations and organizational and other survey issues with the survey and fieldwork coordinators. A written site visit report is prepared to document the observations and discussions.

Earlier experience<sup>21</sup> and experience from the EHES Pilot Project have demonstrated the value of site visits, which serve both the national HES organizes and the EHES RC. National HES organizes will get direct feedback on their work and EHES RC learns how EHES protocols work in different settings and cultures.

For comparability of the lipids and glucose measurements in population level, external laboratory quality assessment is needed to complement the internal laboratory quality control. There are various clinical laboratory standardization schemes in Europe. However, the allowed deviation in these is twice as high as what is desirable for monitoring population distributions. EHES must be able to detect small differences and changes in the population distributions because these can have a major effect on the public health. EQA of the national HES laboratory of each country should be conducted by a single laboratory. This laboratory is standardized

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to the laboratory of the Centers of Disease Control of the USA, which has maintained long-term population study standards since the 1960s.

The EHES RC will collect the data from each country for joint analysis and reporting, and for the evaluation of the data quality. The data will be transferred using standardized protocols and technical tools specifically prepared for this purpose. They will make the transfer secure and easy. Specific attention needs to be paid on data security and confidentiality.

The data to be transferred includes detailed information about (a) the used survey procedures, (b) the selected sample, recruitment history and final participation status of each person selected to the sample, and (c) measurement and questionnaire data for those who participated.

The data will be checked for completeness and consistency, and various quality indicators will be calculated. All shortcomings will be discussed with the respective country and, where possible, errors will be corrected. The results will be included in the evaluation reports.

Basic health indicators will be produced and published together with relevant quality information and interpretation in an appropriate media. Currently, one potential route of publication is the HEIDI Wiki<sup>22</sup> of DG SANCO of the European Commission.

A thorough retrospective evaluation and documentation of each national HES and EHES as a whole serves two purposes. Firstly, it is important to learn from experience and develop the EHES processes continuously. Secondly, those who analyze the data and interpret the results need to know the quality and the country specific characteristics of the data.

The EHES SC will maintain the EHES Database and provide analysis data sets to the research groups which have been granted access to the data. The EHES RC will also manage the data sharing process; including the management and processing of data requests and data transfer agreements, and follow up the progress of the research groups

The budget of 6 M€ for the EHES RC covers the above activities. Included are the staff costs of the head of the EHES RC, a project assistant, 1.5 data managers/systems analysts, 2 statisticians (one of them specialized in survey statistics), one senior and three junior HES experts and a chemist for the laboratory quality assessment. It also includes six training seminars (2 on survey planning, 2 on fieldwork and 2 on data analysis and reporting), two site visits to each national HES, equipment and overheads. In addition to this budget, it is assumed that the hosting institute provides substantial consultative help by experts of various related fields.

*Research*

The budget includes 9 specific multinational research projects, with an average EU-contribution of 750.000 € for each. The purpose of these research projects is to ensure that key questions set for EHES become thoroughly addressed and the results published. It is anticipated that many other research projects utilizing the data will be funded from various sources.



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